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Health promotion and cardiovascular risk reduction among people with spinal cord injury:
physical activity, healthy diet and maintenance after discharge.

(Sub study 1: Prospective Survey of Body Mass Index in People With Spinal Cord Injury)

Health promotion and cardiovascular risk reduction among people with spinal cord injury: physical activity, healthy diet and maintenance after discharge.

Background The incidence of a Spinal Cord Injury in Denmark is 10-15/mill. annually [1]. It is a life changing event that affects all bodily functions below the level of lesion with significant costs for the individual and society, and with consequences that predispose to cardiovascular risk factors such as dyslipidemia, vascular inflammation, insulin resistance, diabetes mellitus type 2, hypertension and overweight. Likewise abdominal adiposity is an independent risk factor for diseases associated with the metabolic syndrome [2]. Cardiovascular disease is one of the most frequent causes of death among people with SCI and occur among 46% of those who have lived for 30 years or more with a SCI, and 35% of people with a SCI who are 65 years or older [3]. The cardiovascular risk factor, including consequences of an inactive lifestyle and weight gain during and after the primary rehabilitation, defines the primary focus of the current project.

The course of overweight

The prevalence of overweight among people with SCI is high and is conservatively estimated to 66% [4]. In a Swedish cohort of wheelchair dependent people with paraplegia, 27- 36% had a cardiovascular risk profile requiring treatment. When Body Mass Index (BMI) adjusted to SCI was entered into the risk model, 80% had a risk profile requiring treatment [5]. Energy expenditure decreases significantly the first weeks after injury and remains low throughout the primary rehabilitation, with the possibility of decreasing even more the following years. Body fat and body weight also decreases in the acute phase, before increasing in the subacute phase towards the same level as before the time of injury [6]. A longitudinal study with participants ranging from 19-60 years of age and neurological level AIS A-D (54% where incomplete at follow up), found an average loss of lean body mass corresponding to 20,5 and 15, 1% in the lower extremities and trunk respectively during the first year after injury. The course among people with SCI during and after discharge from the primary rehabilitation in Denmark is not known. BMI increases gradually, and especially during the first years after discharge from the primary rehabilitation. A Dutch prospective cohort study found that BMI increased gradually with a prevalence of overweight of 28 % during the primary rehabilitation and 54 % at follow up 5 years after discharge [7]. Similar inventories do not exist for people with SCI in Denmark. Obese people with SCI achieve a lower level of functioning during primary rehabilitation than people with normal weight [8], and more knowledge about prevention, treatment and managing overweight among people with SCI is warranted among health care professionals in the clinical setting. [9]. Overweight in people with SCI is associated with increased risk of depression, while physical activity may contribute to a decreased prevalence of depression and increased quality of life [10, 11]. The relationship between these variables in a Danish setting is not known.

Impact of physical activity on health and fitness

In the general population physical activity (PA) is associated with beneficial effects on diseases contributing to the metabolic syndrome including reduced fat mass, and may prevent weight gain as well as maintaining body weight after weight loss, and combined with diet the effect increases [12]. High aerobic capacity has an independent prophylactic effect on comorbidities due to obesity, and greater aerobic capacity is associated with greater cardiovascular health [13]. Until recently the recommendations for PA in the general population has, to a large extent, been the same for people with SCI. A systematic review from 2017 concerning the effect of exercise on fitness level and health among people with SCI, calls for guidelines about frequency, intensity and amount of exercise to enhance fitness and cardiometabolic health [14]. In October 2017, strictly evidence based exercise guidelines for cardiometabolic health was published for the first time,

recommending a minimum of 30 minutes of moderate to vigorous aerobic exercise three times weekly to reduce cardiovascular risk factors. However this recommendation does not include all AIS classifications, people at the age of 65+ or people with an acute SCI due to the lack of sufficient evidence . [15] [16] [17]. However an increased amount of PA in newly injured people with SCI is associated with more favorable lipid profiles and increased VO₂peak during and after discharge from primary rehabilitation [18]. Changes in physical capacity during primary rehabilitation and the years after discharge has previously been described with an increase in VO₂peak of 24% during the early phase of rehabilitation, and with a further increase one year after discharge. Koppenhagen et al found that VO₂peak, despite different trajectories, increased over all in 88% of the participants during a period of 5 years [19, 20]. The course of VO₂peak during and after discharge from primary rehabilitation in a Danish context is not known. After discharge from the primary rehabilitation the amount of PA in people with SCI is varying and 50- 63 % indicates to participate in little or no sports activity on a weekly basis. The majority of those who are physical active are active at mild to moderate intensity (54% and 68% respectively) [10, 15]. Intra- and extra personal factors are influencing participation in PA, including self-efficacy related to being physically active [21]. Therefore a new paradigm is focusing on avoiding inactivity [15]. The amount and intensity of PA in people with SCI in a Danish setting is not known. An association between self-reported PA and adherence to national nutritional guidelines is not necessarily present, and therefore focus on both elements is necessary during lifestyle changes [22].

Prevention and treatment of cardiovascular risk factors

In the literature an interdisciplinary approach to prevention and treatment of cardiovascular risk factors including overweight and obesity among people with SCI with a focus on diet, PA and behavioral interventions is recommended [15] [23]. A multimodal intervention is supported by a qualitative meta- synthesis, where diversity and a combination of several interventions is considered as most effective by people with a movement disability, including people with SCI, in order to promote a physical active lifestyle .Crucial components in the interventions, of which several also acts as outcome measures, are autonomy in relation to decision making related to PA, support and follow up from health care professionals as well as mentors with SCI, information about PA in relation to the diagnosis and finally behavioral interventions using goalsetting and feedback trough physical tests etc. [24]. The conclusion of the systematic review by Greaves et al is identical and states that interventions comprising of diet, PA, social support, increased frequency of follow ups, and the inclusion of goal setting and feedback are most effective to promote weight loss and PA. Besides the above mentioned, the systematic review recommend, on the basis of strong evidence, interventions in the clinical setting that contains both group sessions and individual sessions as well as interdisciplinary interventions that focus on maintaining PA and healthy diet [25].

Several studies have studied the effect of multimodal interventions comprising of diet ,PA and behavioral interventions, or some of these components, in people with SCI and the effect on different outcome measures such as bodyweight, BMI, lean body mass, physical capacity and PA among others and with overall promising results [26] [21, 27] [28].

Chen et al found that an intervention lasting 12 weeks, focusing on weight loss in 16 persons with SCI (AIS A-D) and BMI $\geq 25\text{kg/m}^2$, and consisted of weekly group sessions, where the participants and their partner were educated in nutrition, physical exercise and lifestyle changes, resulted in weight loss in 14 of the 16 participants with an average weight loss of 3,5 kg. 13 participated in follow up and had maintained their weight loss, three had gained weight and six participants had lost additional weight [27]. A RCT- study by Nooijen et al studied the effect of usual rehabilitation including hand biking 3 times weekly for 8 weeks in both groups, and 13 motivational counseling

sessions in the intervention group in order to facilitate PA and found significant effect of the motivational counseling sessions in relation to physical capacity and PA up to 12 months after discharge from primary rehabilitation. This study also explored the participants confidence in being physically active (self- efficacy) and found a strong relationship with physical capacity. A study by Liusuwan et al explored the effect of 16 weeks of group sessions, but also individual sessions, with instruction and education about nutrition, strength training and aerobic exercise, among children and adolescents with SCI and their parents. This study did not find any effect on body weight but found a significant effect in relation to lean body mass and physical capacity. Nash et al explored the effect of a national Diabetes Prevention Program customized to 7 men with SCI who were overweight and prediabetic. The program lasted 6 months and consisted of strength training 3 times weekly, mediterranean diet with a daily calorie intake of 1200-2000 kcal and 16 individual sessions with a lifestyle coach. There was significant effect in terms of reduced BMI and fasting blood glucose as well as increased physical capacity [28].

While writing the project protocol, a user panel consisting of both newly injured as well as experienced people with SCI was established. All the participants were hospitalized at Clinic for Spinal Cord Injuries when they were interviewed about their perception of the present health promoting practice at the clinic. The user panel called for more information in the early phase of rehabilitation about cardiovascular risk, PA and diet as well as more support and guidance about being physical active and appropriate diet, which is the main aim the project.

Hypothesis

Targeted patient education in the form of "Strategic patient education" ¹ in relation to an interdisciplinary, multimodal and patient activating intervention at Rigshospitalet, Clinic for Spinal Cord Injuries (CSCI), is expected to contribute to a decrease of cardiovascular risk factors and maintenance of PA and healthy diet after discharge from the primary rehabilitation.

Purpose

The aim of this Ph.D project is to get an overview of the course of BMI among newly injured people with SCI in Denmark which serves as a historic control in conjunction with a systematic multimodal, intervention study, adapted to a Danish national setting with the aim of reducing cardiovascular risk factors and facilitating PA and healthy diet among all newly injured people with SCI during the primary rehabilitation and after discharge.

Designs (Design description for each sub study).

Sub study 1. Prospective representative longitudinal national survey of Body Mass Index.

Sub study 2. An interdisciplinary multimodal longitudinal controlled intervention study

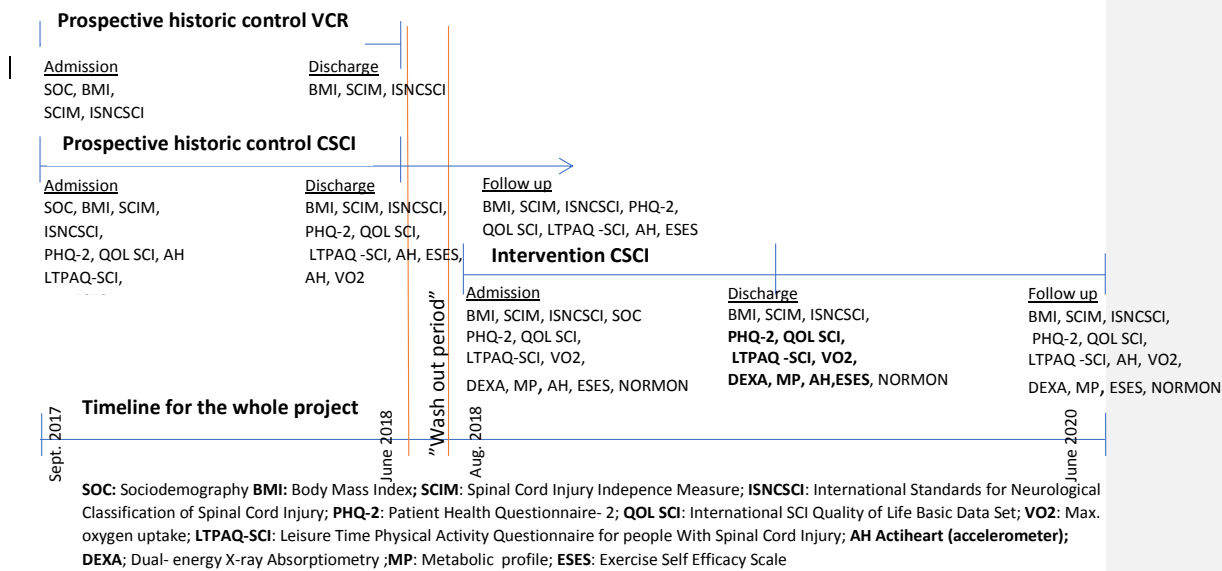
Sub study 3. Test- retest reliability of VO2 peak

Sub study 4. Test-retest reliability of a multi sensor accelerometer.

Methods

¹ Defined as face-to-face interaction between the patient and health care professionals in order to facilitate the patients skills working towards a goal, that requires active patient participation related to decisions for one self and adherence to these. (See description under subproject 2)

Timeline for the project and used outcome measures



Usual rehabilitation today

Usual care during primary rehabilitation today before the intervention study (sub study 2), consists of interdisciplinary rehabilitation provided by doctors, nurses, physio- and occupational therapists, psychologist and social workers with every single profession contributing with their expertise.

According to the masterplan for patient care ("Patientforløbsbeskrivelsen" at Clinic for Spinal Cord Injuries (CSCI)) the patients neurological status (ISNCSCI), level of functioning (SCIM III), bowel and bladder function, cardiovascular and pulmonary function, medication, and psychological state is assessed at admission to CSCI. Non-SCI specific nutritional screening, assessment of body weight and screening for health related outcomes (diet, smoking, alcohol and exercise) is performed as well, but without a systematic approach and follow up.

During rehabilitation, assessment of the above mentioned is repeated, and action is taken (if necessary) in relation to ADL functioning, musculoskeletal challenges including paralysis, spasticity, positioning in bed and wheelchair, as well as mobilization etc. A plan for the rehabilitation is made and adjusted continuously, and includes several of the following elements such as functional training (eg. transfers), strength training, cardiovascular exercise, functional electrical stimulation, wheelchair skills, hydrotherapy, fine motor training of the upper extremities, eg. by creative activities and training of kitchen skills. Also continuously assessment and action is taken in relation to circulation, respiration, thermoregulation, bowel, bladder, skin, pain and spasticity, as well as assessment of the need for aids compensating the level of functioning, including communication aids and splinting. Counseling related to social and economic issues, sexual function and psychological issues is also provided if needed.

During the rehabilitation, different educational workshops for the patients and their relatives about SCI and its consequences are held. Interdisciplinary meetings with the patient every 14 days are

held and goal setting and follow up is made. Evidence based tools for decision making which supports the patients' decisions related to the first weekend at home and also decisions related to bladder management are used. Additionally, mentors with a SCI are available for the newly injured patients. During rehabilitation contact is established to the patient's municipality to ensure the necessary aids, health care and overall support is provided to the patient after discharge from CSCI. Also contact to the national parasport organization is established if desired by the patient and membership of the patient organization is encouraged. During the rehabilitation the patients are in contact with several other medical specialties, and for instance investigations of the urinary tract are performed during the rehabilitation and repeated every 2 years afterwards. Outpatient follow up after discharge with a doctor and if necessary a nurse and physiotherapist is performed every 2 years. Focus on health promotion related to diet, smoking, alcohol and exercise in this setting is described in the masterplan for patient care at CSCI but not how this is carried out systematically.

Although health promotion related to weight, diet, smoking, alcohol intake and physical activity is part of the usual rehabilitation in CSCI, a systematic approach, follow up and feedback is not provided. Assessment of metabolic profile, body composition and physical capacity is not part of the usual care. In the masterplan for patient care at CSCI, health promoting initiatives are described as "communication and conversation with a health promoting purpose with the patient on a daily basis". How the communication is carried out in practice, and whether some health care professionals have a particular responsibility or expertise related to certain aspects of health promotion eg. based on tests or assessments of health, is unclear and not described in detail. A well described and systematic approach related to health care promotion may ensure that all patients at CSCI receive information and knowledge related to health promotion and the risk of cardiovascular disease.

Sub projects

The project consists of a prospective national survey in collaboration with Spinal Cord Injury Centre of Western Denmark and an intervention at CSCI (see the timeline), which results in 4 sub projects

Sub project 1. Prospective representative national survey of Body Mass Index.

This study includes all patients with a new SCI hospitalized at CSCI or Spinal Cord Injury Center of Western Denmark during a period of 9 months whereby 100 patients are expected to participate. On the basis of usual rehabilitation today, data concerning BMI, level of functioning (SCIM III) and neurological status (ISNCSCI) are collected at admission and discharge. At CSCI BMI is collected every 6 weeks. Also the data for quality of life (QoL SCI), depression (PHQ-2), PA (LTPAQ-SCI) and self-assessed ability to be physically active (ESES) will be collected during this period and at follow up 6 months after discharge. A VO₂peak test at discharge is performed and in some patients measurements of accelerometry (AH) will be performed. Patients with a new SCI who are admitted for rehabilitation several months after the time of injury are also included in the prospective survey. Therefore the data for BMI at the time of injury is collected for all patients at admission to primary rehabilitation from both the patient journal and also by asking the patient about weight and height at the time of injury. Data from this subproject serves as a historic control in the Ph.D project.

Sub project 2. A systematic interdisciplinary multimodal intervention which, as a part of usual care, facilitates PA, healthy diet and maintenance after discharge through strategic patient education, with the aim of decreasing cardiovascular risk factors.

This pre- post study includes all patients with a new SCI who are admitted at CSCI during a period of 12- 18 months including follow up. Complete data sets from admission to follow up is expected for approximately 50-60 patients during this period. The multimodal, interdisciplinary, patient activating and patient supportive intervention will be a part of usual care during the project period, and all newly injured patients will receive all the multimodal components, or parts of them, dependent on eg. the level of injury. Rehabilitation of the physical level of functioning and physical capacity will take place unchanged as usual.

A central part of the intervention is to create a uniform and systematic approach when the patients receive information and instructions about cardiovascular risk factors, PA and a healthy diet through targeted strategic patient education, which includes targeted, individualized and systematic, face- to-face interaction between patients and health care professionals, while working towards, and improving a specific health related outcome through adherence to the working processes, medicine and lifestyle. The concept has been used previously for patient education and prophylaxis of catheter related sepsis [44]. Strategic patient education is carried out by all the health care professions in different settings with a focus on clarifying the importance of PA and a healthy diet. This will take place during the individual functional training and rehabilitation in general, and in conjunction with feedback about outcome measures and tests with subsequent instructions. Strategic patient education will also be integrated as a concept in the education of the interdisciplinary health care professionals and mentors with a SCI, as they will be implementing the content of the education into a daily clinical setting.

Pre-intervention education of health care professionals and mentors: Before onset of the intervention, all health care professionals and mentors with a SCI at CSCI will receive information and education about the content and elements of the intervention, cardiovascular risk factors in people with SCI and the effect of PA and healthy diet in order to establish a uniform knowledge at a basic level among all health care professionals and mentors at CSCI as called for in the literature [9]. The sessions are supplemented with evidence based recommendations that can be used by the health care professionals and mentors when they educate the patients. The review by Van Wyk et al emphasizes that patient education is an important part of the interdisciplinary rehabilitation of people with SCI and recommend an individualized approach and the use of different settings in which the patient can receive the education.

Therefore the intervention will include an increased focus on cardiovascular risk factors and systematization of the existing setting and treatment interventions including education of patients- and their relatives in different in different types of forums [45, 46]. New interventions are introduced and several of the outcome measures at admission, discharge and follow up 6 months after discharge are a part of the intervention to facilitate PA and healthy diet through strategic patient education including body weight, body composition, metabolic profile, physical capacity, physical activity, self- assessed ability to be physically active and diet. Also included are instruction and information about PA and the intensity of this by using ratings of perceived exertion, identification of activity and participation problems related to PA and healthy diet using the Canadian Occupational Performance Measure, information about the recommended amount and composition of food on a plate at the lunch and evening servings but also in conjunction with kitchen training and grocery shopping with the occupational therapists. A motivational conversation, tools for decision making, and use of mentors with SCI to facilitate PA and healthy diet are also introduced.

Patient adherence to the elements of the intervention is described descriptively by registration of their participation in the different elements in which they are expected to participate. The adherence of the interdisciplinary health care professionals in relation to the intervention is

described and secured by a process inspired by a previously used prospective effect and process evaluation [47].

Table of interventions, methods, personnel resources, setting and frequency

Interventions in the existing setting	Method	Personnel requirements	Work flow and setting	Frequency
Patient education by the doctors	Education	Doctors	Existing setting and work flows are used and systematized	During the primary rehabilitation
Education cafe	Education	Interdisciplinary		
Education of the relatives	Education	Interdisciplinary		
Cardiovascular exercise and wheelchair skills sessions	Education/ practical	Physiotherapists		
Occupational therapy	Education/practice/goal setting	Occupational therapists		
The Hospital kitchen	Supervision and guidance related to diet composition	Kitchen staff		
Meetings for goal setting	Meeting between the patient and the interdisciplinary health care professionals	Interdisciplinary	Existing setting and work flows are used and systematized	every 14 days
Interventions beyond the existing setting	Method	Personnel requirements	Work flow and setting	Frequency
Education of the health care personnel	Education	Ph.D student + in- and external teachers	All health care personnel	Same lecture x 2 or more before the intervention
Patient Decision Aids	Patient Decision Aids related to physical activity and healthy diet s + use of mentors with SCI	Interdisciplinary	Developed from the existing template	Early stage after admission
Motivational counseling	One session during primary rehabilitation	Selected health care providers with expertise	Provided time and setting	Early stage after admission
Test and outcome measures	Method	Personnel requirements	Work flow and setting	Admission* Discharge* Follow up* After terminated Ph.D project*

Oxygen uptake	VO2peak test	Ph.D student**	Exercise test	X
Objective PA	Accelerometer	Ph.D student**	-	X
Bodyweight	Weighing	Nurses	Existing	X
Body composition	Dexa scan	Secretaries/doctors	Glostrup Hosp.	X
Metabolic profile	Blood sample	Nurse/doctor/secretary	Existing	X
Level of functioning	SCIM	Interdisciplinary	Existing	X
Neurological status	ISNCSCI	Physiotherapists	Existing	X
Depression	Questionnaire	Doctors (admission)#	Existing	X
Quality of Life	Questionnaire	Nurses (discharge)#	Existing	X
Self - reported physical activity	Questionnaire	Ph.D student	-	X
Self- assessed ability to be physically active	Questionnaire	Ph.D student	-	X
Measure of patient participation /shared decision	Questionnaire	Ph.D student	-	X
Measure for a varied and healthy diet in an appropriate amount	Questionnaire	Ph.D student	-	X

*1-2 weeks after admission and before discharge Follow up approx. 6 months after discharge.

** Is handled by physiotherapists with knowledge and skills after the project.

Is handled by the Ph.D student at discharge and admission for depression and quality of life respectively.

Subproject 3. Test- retest reliability of a VO2 peak test

This study includes all patients participating in subproject 1 who are able of performing the test. A seated cross-trainer is used (NuStep T5XR) with an incorporated test protocol in the equipment software. Equipment and protocol is reliable in people with traumatic brain injury and has been validated in healthy persons [32, 33]. In people with an incomplete SCI the equipment is safe, and involves a large amount of muscle mass ensuring completion of the test [34]. The equipment may also be used by patients with a complete SCI of the lower extremities, but in case the equipment is difficult to use for people with a complete tetraplegia, an armcranking ergometer will be used (SCI FIT Pro1). The reliability of the cross-trainer has not previously been evaluated in people with SCI. The test- retest study takes place at discharge, separated by 48 hours or within maximum 5 days at the same time of the day. The participants refrain from caffeine, alcohol and intensive physical exercise on the day of testing as well as tobacco smoking to hours before the test. Bladder emptying is taken care off before the test.

Subproject 4. Test-retest reliability of a multi sensor accelerometer.

This study includes a subsample of 20 patients participating in subproject 1. The equipment used for monitoring amount and intensity of PA consists of sensors registering acceleration and heart rate and is placed on the thorax of the participant with two surface electrodes. The equipment has previously been used in wheelchair dependent people with SCI, although the reliability of the equipment has not previously been assessed [35]. The precision of the equipment is higher when calibrated individually to the participant using an exercise test [68]. In this project individual calibration will be made during the exercise test described in subproject 3, and continuous measurements of amount and intensity of PA will be made during a period of 24 hours. The test-retest is performed at discharge, separated by 48 hours or within maximum 5 days at the same time of the day.

Outcome measures

All outcome measures will be collected at admission, discharge and follow-up 6 months after discharge. At CSC data for BMI is also collected every 6th week during the hospitalization period.

Primary outcome

Oxygen uptake: Is measured as VO₂peak during a maximal exercise test and is gold standard for measuring aerobic capacity. For people with a SCI several test protocols have been used [36]. The test in this project is performed by using the integrated test protocol in the software of NuStep XR5 or SCI FIT Pro 1. Gradual increments in workload is added every minute depending on the level of lesion. The participant maintains a fixed cadence until predefined criteria for VO₂peak is reached after 8-12 minutes. If VO₂peak is not reached during this period the workload increases each minute until VO₂peak [36, 67]

Secondary outcomes

Objective physical activity: Is measured in a sub-sample in the historic control cohort and the participants in the intervention study with a multisensor device (Actiheart®) recording accelerations and heart rate. It is previously used for wheelchair users with a SCI and individual calibration is important to get the most accurate data [29].

Bodyweight: Is measured as Body Mass Index (BMI) which is the most widely used outcome measure for measuring bodyweight in people with SCI. BMI is not sensitive enough to distinguish between fat mass and lean body mass nor overweight in people with SCI. Lowering the cut-off for overweight to 25kg/m² the sensitivity increases although this adjustment is not used consequently in the literature [30]. BMI is already collected as part of the existing routines every week and data for BMI every 6th week until discharge will be included in the project. Some newly injured are admitted to primary rehabilitation several months after the time of injury, and the course of bodyweight may already have changed significantly since the time of injury. Therefore BMI at the time of injury is collected from the patient journal from the initial hospitalization during the acute stage and by asking the patient at admission to primary rehabilitation about the height and weight at the time of injury.

Body composition: Is determined by Dual energy x-ray absorptiometry (Dexa) which is gold standard for assessing obesity and body composition although cut-off values for people with SCI has not been established [30].

Metabolic profile: Consists of CRP as a marker for inflammation, BP, Lipid profile: Total cholesterol, Triglycerides, HDL cholesterol, LDL cholesterol which all are included in the International SCI Endocrine and Metabolic Function Basic Data Set, as well as Hemoglobin A1c as

a marker for carbohydrate metabolism, and is included in the International SCI Endocrine and Metabolic Extended Data Set [31, 32].

Level of functioning: Is determined by the Spinal Cord Injury Independence Measure III (SCIM III) which is a valid and reliable outcome measure designed to assess level of functioning in people with SCI in a clinical setting and in research [33] [34, 35]. The SCIM is composed of 19 items that assess 3 domains. 1 Self-care (6 items, scores range from 0-20). 2 Respiration and sphincter management (4 items, scores range from 0-40). 3 Mobility (9 items, scores range from 0-40). The total SCIM scores range from 0 to 100. SCIM III is already collected as part of the existing routines at CSCI.

Neurological status: Is determined by the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) and is the most widely used classification in people with SCI [36, 37]. The classification tool involves a sensory and motor examination to determine the neurological level of the injury and whether the injury is complete or incomplete. The ISNCSCI defines neurological level as the most caudal level at which sensory and motor function are intact. The completeness of the injury is graded according to the ASIA Impairment Scale (AIS). AIS is used to determine the degree of motor and sensory function below the level of the SCI. A complete or incomplete injury is defined as absence or presence of sensory and motor function in the most caudal sacral segment. A = complete; B = sensory incomplete without motor function > 3 levels below the motor level of injury on both sides of the body; C = motor incomplete, with preserved motor function below the level of injury and where > 50% of the key muscles below the injury level have a degree < 3 by MMT; D = motor incomplete with preserved motor function below the level of injury and where > 50% of key muscles below the injury level have a degree > 3 by MMT; E = normal sensory and motor function in all segments. ISNCSCI Is already collected as part of the existing routines at CSCI.

Depression: Is measured by the Patient Health Questionnaire- 2 (PHQ-2) which is a generic outcome measure for measuring depression. In people with SCI a cut-off score of 3 is associated with a sensitivity of 83,3% and specificity of 95,7% [38]. PHQ-2 is already collected at admission as part of the existing routines at CSCI

Quality of Life: Is measured by the International SCI Quality of Life Basic Data Set (QoL SCI) which consists of three questions regarding satisfaction with life in general as well as physical and mental health. It is a valid outcome measure with good internal consistency [39] [40]. QoL SCI is already collected at discharge as part of the existing routines at CSCI.

Self - reported physical activity: Is measured by the Leisure Time Physical Activity Questionnaire for people with Spinal Cord Injury (LTPAQ-SCI) which is a self- administered questionnaire concerning leisure time PA, including amount and intensity the past 7 days. LTPAQ-SCI uses a scale for perceived exertion which is validated against VO₂-peak and the Borg-scale. Reliability and validity of the self- reported activity level is satisfactory in the moderate and high intensity area [13]. For people hospitalized during primary rehabilitation, defining leisure time may be difficult. Therefore an instruction defining leisure time in this context was formulated describing leisure time PA as being PA that is not part of the patients weekly schedule, is not planned together with the health care professionals as part of the rehabilitation and is not self- administered exercise which is planned or scheduled as part of the rehabilitation. Therefore leisure time PA is any kind of spontaneous PA that is not planned or schedule together with a physiotherapist or other health care professionals. This kind of necessary PA is described in the additional question developed for the study. The question will be designed as the original questions and the same intensity scale is used.

Self- assessed ability to be physically active: Is measured by the Exercise Self Efficacy Scale for people with Spinal Cord Injury (ESES) which is an outcome measure developed for assessing self- efficacy related to PA in people with SCI, and consists of 10 questions which are answered on a 0-4 scale. ESES is reliable with a high internal consistency (Cronbach's alpha 0,94). Also content validity in the form of face and construct validity are satisfactory [41].

Measure of patient participation /shared decision making

Measure for a varied and healthy diet in an appropriate amount: Is measured by the Nordic monitoring of diet, physical activity and overweight (NORMON). The questionnaire is used to measure the course in dietary habits and explores how often 16 food indicators are consumed. The food indicators are chosen in a way that reflects the diet's nutritional quality. An association between the frequency of food indicator intake and the overall nutritional value of the diet is present. Several of the chosen food indicators are recommended in the national nutritional recommendations, and through the questions, it is possible to achieve knowledge about how many of the participants who eat fish twice a week, how many who eat six pieces of fruit or vegetables a day etc. The questionnaire was validated in 2009 against existing questionnaires about diet [42]. The outcome measure is developed in a Nordic collaboration and has been used for common monitoring of the diet habits, physical activity level and overweight of the Nordic population in 2011 and 2014 [43]. In the Ph.D project the questions related to alcohol intake and smoking are also used.

Feltkode ændret

Clinical implications of the project

The project will contribute to a uniform and increased focus as well as knowledge among the interdisciplinary health care professionals at CSCI and VCR, about preventing cardiovascular risk factors and health promotion. The project will also contribute to organizational changes including implementation of new work flows and knowledge about how these changes all together contributes to the initiation and maintenance of PA and healthy diet. Even though new treatment initiatives are introduced, a lot of the existing workflows and settings are used and the intervention or major parts of this is expected to continue as a part of the standard treatment at CSCI after the project is terminated, and hopefully contribute to prevent cardiovascular disease in future newly injured people with SCI.

Name of the investigator and trial site

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Feltkode ændret

Trial registration

The project is reported to the Danish Data Protection Agency

Data storage

Informed consent is obtained by the Ph.D student in conjunction with the procedure for recruitment of participants (see later).

Data from the patient journals in Epic and the different outcome measures used, is stored in a web based database (Redcap) which is created by the regional Centre for IT, Medico and Telephony (CIMT), with limited access and ID- code, to which pseudo anonymized data is transferred directly,

or via an encrypted USB-stick. An identification list is stored in a locked cabinet at CSCI, local 3403.

Data is stored until December 31, 2027 after which paper material is shredded and data files are deleted.

Statistics

The intervention study and follow up is performed as a pragmatic study and includes, with a few exceptions, all newly injured patients with SCI admitted to primary highly specialized rehabilitation at CSCI. Patients will be included during a time period of 18 corresponding to approximately 40 – 60 patients. Due to the rareness of the morbidity a power calculation is not performed for the primary outcome prior to the intervention, but it is assumed that the total participant number in the intervention and in the historic control cohort, will be comparable to the existing scientific literature.

Numeric continuous data collected at admission, discharge and follow up is reported descriptively as mean and standard deviation together with 95% confidence intervals, or as median, upper and lower quartile as well as interquartile range. Changes over time is reported on the basis of paired t-test. In subproject 3 and 4 the reliability of the outcome measures is analyzed by paired t-test, Pearsons product moment correlation and coefficient of variation or Intraclass correlation coefficient between the test- retest sessions.

Participants, inclusion- and exclusion criteria

Inclusion criteria: All newly injured patients within the previous 12 months, with a SCI and admitted at CSCI are included, regardless of age, neurological level of lesion and completeness of the injury. In subproject 1 all newly injured people with SCI admitted at VCR are also included. Patients under the age of 18 will participate if informed consent is retrieved from their parents.

Exclusion criteria: Insufficient skills in Danish language and reduced mental function that prevents reading and answering the questionnaires. For the VO₂peak test: Motor complete SCI (AIS A and B) at C4 level or above and assisted ventilatory function. Other exclusion criteria are the presence of decubitus, severe spasticity or musculoskeletal problems considered at risk of aggravation during testing or preventing completion of the test.

Recruitment of participants:

All newly injured patients who are admitted for rehabilitation at CSCI during the project period are included in the intervention (subproject 2) as it becomes a part of usual care during the project period. The Ph.D student is informed about new and future admissions at CSCI by local patient lists every week, and LTPAQ-SCI, ESES, QoL_SCI and NORMON is handed out to the patient and collected again by the Ph.D student. Date and time for the VO₂peak test is handed to the patients physiotherapist, who will make sure to enter it into the patients weekly schedule. The same procedure is repeated at discharge except that QoL_SCI is collected as a part of existing procedures and PHQ-2 is collected by the Ph.D student. In subproject 1, data for VO₂peak at CSCI will only be collected at discharge. All newly injured patients who are admitted for rehabilitation at VCR in the same period are recruited for subproject 1 and data for BMI, SCIM III and ISNCSCI is collected as a part of existing procedures in usual care.

The coordination related to booking of the DEXA-scan and transportation for this is managed by the secretaries. Ordination of the DEXA-scan as well as blood samples related to metabolic profile is handled by the doctors.

Ethical considerations

During the intervention period all newly injured patients who are admitted for rehabilitation are offered the treatment and tests included in the intervention to the extent they are able to participate depending on eg. the level of lesion and completeness of the injury, as this is a part of usual care and will continue as a part of usual care after termination of the project. The regional ethical committee will be contacted to clarify the need to report sub project 2 while the intervention in the project is closely related with the content of the present rehabilitation, why the risk of pain and discomfort related to the elements in the intervention is considered modest. Patients who are re-hospitalized for control visit will not be a part of the project and will receive usual rehabilitation.

During the VO₂peak test, there will be special attention on symptoms of autonomic dysreflexia (AD) in people with SCI above T5-6. Several symptoms may be present and include a 20mm Hg increase in systolic blood pressure above baseline, headache, flushing and cold sweating above the level of injury. In this case the exercise test is disrupted and relevant actions are initiated, such as loosening of tight clothes, an upright positioning depending on the severity of AD. If the exercise test results in orthostatic hypotension (OH) the test is disrupted and the patient is placed in a horizontal position with elevation of the lower extremities above heart level.

Any unintended events related to the elements of the intervention is reported according to existing guidelines.

It is assumed that any risks is by far surpassed by the therapeutic gains such as an expected risk reduction of cardiovascular disease and consequently mortality.

Funding and organization

This work was supported by a mutual cooperation about the research program "Centre for Integrated Rehabilitation of Cancer Patients (CIRE) - Neuro/Psychology", between the University Hospitals Centre for Health Care Research (UCSF), University hospital Copenhagen, Rigshospitalet, Blegdamsvej 9, section 9701 (Ryesgade 27, DK- 2100 Copenhagen); the Metropolitan University College (Metropol), Institute for Nursing, the Health and Technological Faculty, Tagensvej 86, DK- 2200 Copenhagen and the NeuroScience Centre, section 2091; Rigshospitalet, Blegdamsvej 9, DK- 2100 Copenhagen; Neurologic department, Nordsjællands Hospital and Psychiatric centre, Glostrup Hospital.

The initiative behind the neuro/psyk programme consists of researchers and leaders from UCSF and Metropol, as well as the steering committee of UCSF consisting of representatives from the hospital directors in the Capital region (Vicedirector for University hospital Copenhagen, Rigshospitalet Helen Berndt Andersen, hospitalsdirector for Nordsjællands hospital Bente Ourø, vicedirector for the psykiatri in the capital region Anne Hertz, and associate dekan Metropol Randi Brinckmann Wiencke).

The project group in relation to the Ph.D projektet consist of senior researcher Tom Møller (UCSF, head supervisor), professor Fin Biering-Sørensen (Neuroscience centre Rigshospitalet, Clinic for Spinal Cord Injuries, co-supervisor), Docent Lone Schou (Metropol, co- supervisor), professor Lis Adamsen (UCSF), senior researcher Julie Midtgaard (UCSF), head nurse Hanne Folden Lindholdt (Clinic for Spinal Cord Injuries), leading therapist Janni Sleimann (Clinic for Spinal Cord Injuries)

Clinic for Spinal Cord Injuries), clinical nurse specialist Line Dalsgaard (Clinic for Spinal Cord Injuries) and center manager nurse (Vibeke Freilev (Neuroscience centre, Rigshospitalet.

Interests of conflict

The Ph.D student has no interests of conflict related to the project in general or any of the subprojects

Risk assessment and changes to the protocol

The completion of the Ph.D project may come in danger if the intervention elements and workflows are not implemented by one or several of the interdisciplinary professions, or if the necessary data are not collected by the interdisciplinary professions. If this appears to be the case during collection of data from the patients journal in Epic or it is expressed by the staff at staff meetings, the responsible department managers will be informed in order to ensure the implementation of the elements.

The Ph.D project may also come in danger if the patients are engaged in other research projects parallel to the Ph.D project, which is considered to be most likely, but since the Ph.D project comprises the patients standard treatment, the risk that the patients participation in other research projects will affect the Ph.D project is considered modest. Also the Ph. D project may come in danger if the patients does not consent to the use of their data in the project.

A significant challenge to the project, and a factor able to impact on the projects completion is the logistic planning related to the patients having the necessary tests made at the right times at admission, discharge and follow up, for which they need to be called in for.

Some of the data used in project and many of the settings and work flows used in the intervention is a part of the existing settings and procedures, which is ensuring the completion of the project.

At Clinic for Spinal Cord Injuries the clinic management by head nurse Hanne Folden Lindholdt, leading therapist Janni Sleimann and head of the clinic Claus Andersen are responsible for ensuring the setting necessary for completing the project and its elements. At an overall level center manager nurse Vibeke Freilev, Neuroscience centre, Rigshospitalet is responsible for ensuring the necessary setting for the completion of the project.

Changes to the protocol will be described in an additional protocol.

Publication of results:

Attempts will be made to publish the projects results in relevant scientific journal such as BMJ Open, Archives of Physical Rehabilitation Medicine, Journal of Spinal Cord Medicine and Spinal Cord. Listed below are the preliminary titles of the articles.

The Ph.D student will be primary author on all articles primary supervisor Tom Møller will be last author on articles related to subproject 2, 3 and 4, while co- supervisors Fin Biering-Sørensen and Lone Schou are last authors on articles related to subproject 1 and the protocol article respectively. Clinical nurse specialist Line Dalsgaard is co- author on the protocol article and the article related to subproject 1

Protocol article: Health and Cardiovascular Risk Reduction in People with Spinal Cord Injury - Physical Activity, Healthy Diet and Adherence after Discharge from Primary Rehabilitation.

1. Longitudinal National Survey of Body Mass Index and Measures of Functional Recovery, Depression, Quality of life, Physical Activity and Exercise Self Efficacy during Inpatient Spinal Cord Injury Rehabilitation and Follow Up.
2. Effects of a Systematic and Interdisciplinary, Multimodal and Patient Engaging Intervention on , Metabolic Markers, Body Composition, Physical Activity and Diet, Quality of Life and Exercise Self Efficacy during Inpatient Rehabilitation with Follow up, Facilitating Adaptation to Physical Activity and Healthy Diet in People with Spinal Cord Injury.
3. Test-retest reliability of VO2 peak using a recumbent stepper in persons with spinal cord injury.
4. Test-retest reliability of a multi sensor device monitoring amount and intensity of physical activity in spinal cord injured persons during inpatient rehabilitation and at follow up.

In relation to subproject 2 there may be a possibility to prepare an article in collaboration with Sunnaas Sykehus in Oslo, Norway, where a planned Ph.D project has the same overall focus. Results for SCIM III, ISNCSCI, VO2peak, BMI, Metabolic profile, DEXA and QoL SCI in the two projects may be published.

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